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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,364	04/02/2001	Ismat Ullah	HX96 (DIV)	7174

7590

06/06/2003

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/06/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824364

Applicant(s)

ULLAH

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/28/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 28-47 is/are pending in the application.
- Of the above claim(s) 29-35 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 28, 36-47 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 1, 4
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Applicant's election of Group II and a method of using granules in Paper No. 5 and 8 respectively are acknowledged. Because applicant did not distinctly and specifically point out the any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28, 41, 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisman et al.

Eisman et al teach a method of lowering cholesterol by administration is a combination of an HMG CoA reductase inhibitor and a pharmaceutical which reduces cholesterol other than by inhibiting HMG CoA reductase (abstract), Lovastatin (column 8 lines 56-59) and aspirin (column 13 line 42) are disclosed. Tablets and capsules are disclosed (column 15 line 10). Antioxidants such as ascorbic acid are disclosed (column 15 line 14).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28, 36-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisman et al in view of Eichel et al and Hodges et al.

Eisman is discussed above.

Eichel et al., teach sustained release preparations of aspirin wherein the aspirin is uncoated as well as coated with an enteric coat (abstract). Granular drugs are specified (column 5 line 65).

Hodges et al., teach enteric-coated pellets (abstract). Pravastatin is specified (table, column 5).

It would have been obvious to one of ordinary skill to deliver the composition of Eisman et al with the vehicle of Eichel et al., to achieve the beneficial effect of controlled release. As to coating statins as well, Hodges et al., teach such.

Claims 28, 36-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants provide no evidence of "Preventing" in claim 46.

No claims allowed.

Item ~~PM~~^{AM} on the PTO form 1449 supplied with paper #4 has been lined through because only the odd numbered pages were supplied.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR
May 22, 2003


A rectangular stamp with the following text:
EXAMINER
S. PADMANABHAN
ART UNIT 1617
MAY 22 2003